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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,543	12/13/2001	Gerhard Hartwich	PATKRI P01AUS	9206
20210	7590	08/30/2005	EXAMINER	
DAVIS & BUJOLD, P.L.L.C. FOURTH FLOOR 500 N. COMMERCIAL STREET MANCHESTER, NH 03101-1151			RILEY, JEZIA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	.09/856,543	HARTWICH ET AL	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 71 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71 and 84-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Remarks***

1. Applicants' arguments, filed on 6/23/05, have been approved and entered. They have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 102/103***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1637

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 71, 84-88 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thorp et al. (US 5,968,745).

Thorp et al. discloses a polymer-electrode including (a) a substrate having a conductive working surface; and (b) a polymer layer on the conductive working surface.. An oligonucleotide probe can be attached to the polymer layer and is available to capture target nucleic acid. A soluble mediator can diffuse freely and transfer electrons from the preselected base in the hybridized nucleic acid to the conductive working surface of the substrate. An electronic signal generated from the electron transfer reaction is detected and quantitated. (abstract and examples).

As schematically illustrated in FIG. 1, the method, which may be used for detection of a preselected base on a target nucleic acid, comprises (a) contacting the test sample to an oligonucleotide probe that specifically binds to the target nucleic acid to form a hybridized nucleic acid; (b) contacting the hybridized nucleic acid to a transition metal complex that oxidizes the preselected base in an oxidation-reduction

Art Unit: 1637

reaction (which is viewed as the attachment of the redox-active substance of instant claim 71); (c) detecting the presence or absence of the oxidation-reduction reaction associated with the hybridized nucleic acid; and (d) determining the presence or absence of the target nucleic acid in the test sample from the detected oxidation-reduction reaction at the preselected base. As illustrated in FIG. 1, the oligonucleotide probe may be immobilized on a solid support. Alternatively, the oligonucleotide probe may be provided free in solution, and other means provided to separate the hybridized nucleic acid from the sample (e.g., by a mediator nucleic acid that binds to the oligonucleotide probe, or by a biotin-avidin binding interaction, where biotin is bound to the oligonucleotide probe and avidin is immobilized on a solid support). The oxidation-reduction reaction, and any step up to the detection step may be done on the polymer layer before or after the polymer layer is brought into contact with the conductive working surface of the substrate. Which is viewed to be inclusive of the further chemical compounds of instant claims 85-87 (col. 12, lines 40-68).

After hybridization, the hybridized nucleic acid is reacted with a suitable mediator which is capable of oxidizing a preselected base in an oxidation-reduction reaction. The mediator may be any molecule such as a cationic, anionic, non-ionic, or zwitterionic molecule which is reactive with the preselected base at a unique oxidation potential to transfer electrons from the nucleic acid to the electrode. Thus the selection of mediator will be dependent upon the particular preselected base chosen, and will be readily determinable by those skilled in the art. Particularly preferred mediators include transition metal complexes which are capable of metal-nucleic acid electron transfer

Art Unit: 1637

with the preselected base such that the reduced form of the metal complex is regenerated, completing a catalytic cycle. To effect the oxidation-reduction reaction of the mediator with the preselected base, the mediator may be reacted with the hybridized nucleic acid according to any suitable technique. All that is required is that the mediator be reacted with the hybridized nucleic acid sample under conditions sufficient to effect the selective oxidation of the preselected base. (col. 8-10).

Claims 84-88 have added functions which the prior art has not analyzed such as the thermally dehybridised step in instant claim 84); but given the above 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition, because one skill in art in order to be able to reuse the probe or the target will inherently thermally dehybridized the double strand hybrid for further steps or assays.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare and use composition which appeared to be identical, the prior art therefore suggests the instant application under 35 U.S.C. § 103(a).

Art Unit: 1637


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786.

The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/27/05



**JEZIA RILEY**  
**PRIMARY EXAMINER**